



Selected Rules Subject to Delay under Regulatory Freeze Memorandum

Updated: January 29, 2021

A memorandum issued by White House Chief of Staff Ron Klain on Inauguration Day allows the Administration to consider delaying the effective date for 60 days of any rules published in the *Federal Register* – or issued in any manner – that have yet to take effect.¹ Such delays require proactive action by the Administration and are not effectuated by default.

Any such 60-day delay applies from the date of the memorandum (i.e., January 20, 2021). The memorandum further allows agencies to reopen a 30-day comment period on any delayed rules to consider substantive policy issues, upon which the agencies may decide to further delay the effective date under the memorandum or through notice-and-comment procedures. After such delays, the agencies may opt to take no action or consult with the director of the federal Office of Management of Budget on further action that would likely necessitate notice-and-comment rulemaking (e.g., withdrawing or modifying provisions). The memorandum applies widely to rulemaking and guidance.

In the following chart, we highlight rules already subject to a delay of their effective date under the memorandum as well as selected rules potentially subject to such delay because they are not yet in effect:

Regulation	Effective Date	Applicability Date	Potential Next Step
<i>Already Delayed through a Federal Register Announcement</i>			
HHS OIG Final Rule Eliminating Safe Harbor Protection for Drug Rebates in Medicare Part D	1/29/2021	1/1/2022	<ul style="list-style-type: none">• 60-day delay published 1/29/2021 delaying the effective date (not the applicability date) of certain provisions until 3/22/2021²• Notice of delay cited cause to delay under WH memorandum and PCMA litigation to overturn rule³ and vacate effective date⁴

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/>

² <https://public-inspection.federalregister.gov/2021-02132.pdf>

³ <https://www.pcmanet.org/wp-content/uploads/2021/01/PCMA-Complaint-US-District-Court-for-the-District-of-Columbia.pdf>

⁴ <https://www.pcmanet.org/wp-content/uploads/2021/01/Rebate-Rule-Motion-for-Partial-Summary-CB.pdf>

Regulation	Effective Date	Applicability Date	Potential Next Step
			<ul style="list-style-type: none"> OIG may subsequently reopen 30-day comment period under memorandum, though separate notice needed Potential for repeal of final rule to be used as offset in COVID relief package (\$177B in CBO-scored savings)⁵
CMS Final Rule on Secure Electronic Prior Authorization for Medicare Part D Program	2/1/2021	NCPDP SCRIPT standard required 1/1/2022; allowed as of 1/1/2021	<ul style="list-style-type: none"> 60-day delay published 1/29/2021 delaying the effective date (not the deadline for the transaction standard) to 3/30/2021⁶ CMS may subsequently reopen 30-day comment period under memorandum
CMS Final Rule on Organ Procurement Organizations Conditions for Coverage	2/1/2021	8/1/2022 for new outcomes measures	<ul style="list-style-type: none"> 60-day delay published 1/29/2021 delaying the effective date to 3/30/2021⁷ In the same notice, CMS reopens a 30-day comment period on the rule
HRSA Proposed Rule on Implementation of Executive Order on Epi-Pen and Insulin Pricing	1/22/2021	1/22/2021	<ul style="list-style-type: none"> 60-day delay published 1/26/2021 delaying the effective date until 3/22/2021⁸ HRSA may subsequently reopen 30-day comment period under memorandum
<i>Selected Rules Potentially Subject to Delay under Regulatory Freeze</i>			
CMS Interim Final Rule (IFR) on Most Favored Nation Demonstration for Medicare Part B Drugs	11/27/2020	1/1/2021	<ul style="list-style-type: none"> Effectively frozen by U.S. District Court for Northern District of California, which vacated the IFR pending completion of notice-and-comment rulemaking⁹ Could be formally withdrawn or modified through notice-and comment rulemaking by Biden-Harris administration

⁵ <https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf>

⁶ https://public-inspection.federalregister.gov/2021-02181.pdf?utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov&utm_medium=email

⁷ https://public-inspection.federalregister.gov/2021-02181.pdf?utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov&utm_medium=email

⁸ https://public-inspection.federalregister.gov/2021-01629.pdf?utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov&utm_medium=email

⁹ <https://innovation.cms.gov/media/document/mfn-ca-50-order-prelim-injunct>

Regulation	Effective Date	Applicability Date	Potential Next Step
Calendar Year (CY) 2022 Medicare Advantage and Part D Technical Changes Final Rule	3/22/2021	1/1/2022, except for select provisions (e.g., real-time benefit tools) apply 1/1/2023	<ul style="list-style-type: none"> 60-day delay of effective date possible Any reopening of 30-day comment period pursuant to regulatory freeze memo likely would necessitate finalization of provisions by June 2021 bid deadline
CY 2022 Medicare Advantage Final Rate Announcement	Subregulatory	1/1/2022	<ul style="list-style-type: none"> Unclear, though subject to potential 60-day delay Any reopening of 30-day comment period pursuant to regulatory freeze memo likely would necessitate finalization of provisions by June 2021 bid deadline
Medicaid Value-based Purchasing (VBP) Final Rule	3/1/2021	<p>Generally 3/1/2021, though 1/1/2022 for line extension changes, multiple best prices</p> <p>1/1/2023 for exclusion of accumulator programs from best price</p>	<ul style="list-style-type: none"> 60-day delay of effective date possible with additional 30-day comment period
CY 2022 Final Payment Notice	3/15/2021	1/1/2022	<ul style="list-style-type: none"> 60-day delay of effective date possible Any reopening of 30-day comment period pursuant to regulatory freeze memo likely would necessitate finalization of provisions by June 2021 filing deadlines for qualified health plans
CMMI Part D Modernization Model	Subregulatory	1/1/2022 for new formulary provisions affecting protected classes and one drug/category or class	<ul style="list-style-type: none"> No notice-and-comment procedures necessary if CMMI decides to modify parameters at any time
HHS Securing Updated and Necessary Evaluations Timely (SUNSET) Final Rule	3/22/2021	Same; HHS will have five years from this final rule's effective date to assess a rule that is more than 10 years old	<ul style="list-style-type: none"> 60-day delay of effective date possible Likely to be withdrawn through notice-and-comment rulemaking